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PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, September 23, 2015 at 9:00 a.m.**
PLACE:	**Buena Vista Conference Center, Dining Room, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	Approved December 2, 2016

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Philip Kim, M.D., Medical Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Stephen Ruggles, PA-C, PA Representative
Mark Hanna, Public Representative

MEMBERS ABSENT

Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Art Jankowski, VMD, Veterinary Representative
Alex Zarow, R.Ph., Pharmacy Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
David Mangler, Director, Division of Professional Regulation
Samantha Nettesheim, Pharmacist Administrator

ALSO PRESENT

Tejal Patel
Ray Hancock
William Thompson
Jean Binkley
Jonathan Higgins
Roopa Bhat
Jeanne Chiquoine
Deborah Hamilton

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:05 am.

REVIEW AND APPROVAL OF MINUTES

The review and approval of the July 29, 2015 was tabled until the next meeting.

PRESIDENT'S REPORT
No Report

UNFINISHED BUSINESS
Deliberations on Proposed Addition of Regulation 11.0 Safe Opiate Prescribing – The Committee received written comments from Attorney General Matt Denn; Bob Twillman, American Academy of Pain Management; and Nancy Fan, President Medical Society of Delaware. Many of the comments received had been discussed during previous Controlled Substance meetings. The Committee went into deliberations to review all submitted verbal and written comments. The Committee made many amendments to the proposed regulation including but not limited to the addition of 9.5.9.3 "More frequent query of the PMP and testing may be required for high risk patients". Ms. Kelly will draft the amendments which will be reviewed at the next Committee meeting.

Request to Lift Suspension Re-Review – Jean Binkley – The Committee reviewed additional information submitted by Ms. Binkley at their request. A motion was made by Mr. Kremer and seconded by Dr. Kim to recommend to lift the suspension. The motion carried unanimously.

Non-Photo ID Cards – After further discussion, the Committee requested Ms. Kelly and Mr. Dryden to develop amendments to Regulation 4.10 to include federal (military) ID's and language that would permit the obtaining of medications without ID in hospital discharge settings. Proposed language will be reviewed at the next Committee meeting.

Re-Review Consent Order Agreement – John Pearson – After review, a motion was made by Dr. Kremer and seconded by Mr. Von Goerres to approve the consent order as written. The motion carried unanimously.

NEW BUSINESS
Review Consent Agreement – David Kalkstein – After review, a motion was made by Dr. Kremer and seconded by Mr. Hanna to approve the consent order as written. The motion carried unanimously.

DIRECTOR'S REPORT
Mr. Dryden will be attending the NASCSA annual meeting in October. At that time he will be presenting an update report on the University of Delaware geo-mapping project.
He reported that the Office of Controlled Substances has been working with the DEA and FDA on various drug cases.
Mr. Dryden along with the DEA is in the process of registering dog handlers from New Castle County and Dover Police Departments.

Case/Diversion Review
None

PMP Review
None

Current Event Review
DEA to Hold 10th Prescription Drug Take-Back Day This September
To help the fight against prescription drug abuse and diversion, Drug Enforcement Administration (DEA) has announced that it will bring back the National Prescription - DEA Acting Administrator Chuck Rosenberg today announced that the 10th National Prescription Drug Take-Back will take place September 26th from 10 am-2 pm local time in every state but Pennsylvania and Delaware, where the event will take place on September 12. As with the previous nine Take-Back events, sites will be set up throughout communities nationwide so local residents can return their unwanted, unneeded, or expired prescription drugs for safe disposal. Collection sites in every local community can be found by going to www.dea.gov . This site will be continuously updated with new take-back locations.
FDA Releases Draft Guidance on Naming System for Biological Products, Seeks Public Comment

To ensure the safe use of biological products, Food and Drug Administration (FDA) has developed draft guidance for industry on the nonproprietary naming of biological products. The draft guidance, "Nonproprietary Naming of Biological Products," (PDF) details the FDA's proposed naming convention that is intended to prevent inadvertent substitution of biological products that are not interchangeable and to support the safety monitoring of post-market products, according to an FDA Voice blog post. FDA seeks public comment regarding the proposed naming convention, and has also requested public comment on the "benefits and challenges of other naming approaches."

Web Search Engine to Warn About Fake Online Pharmacies

To help consumers avoid potentially unsafe online drug outlets, Bing will provide a new warning message on certain search results in Bing.com. "This warning will appear if a Bing user clicks on a pharmaceutical site that has been cited by the FDA as a fake online pharmacy engaged in illegal activity, such as offering dangerous, unapproved and misbranded prescription drugs to US consumers," indicates Bing in a blog post. The warning message informs consumers that FDA has issued a Warning Letter to the site about potentially unsafe drugs and presents consumers with a link to more information about choosing a safe online pharmacy.

New Drug Technologies Promise to Support Patient Safety

Three-dimensional printing (3DP) technology is being used to create a pill that delivers an optimal dose and is easier for patients to consume. FDA has approved the first oral prescription drug made using 3DP technology. SPRITAM® levetiracetam is used as a prescription adjunctive therapy in the treatment of partial onset seizures, myoclonic seizures, and primary generalized tonic-clonic seizures in adults and children with epilepsy, according to the manufacturer's press release. SPRITAM enhances the way patients experience taking medication because Aprecia's ZipDose Technology enables delivery of the largest strengths, up to 1,000 mg in a single dose, with just a sip of liquid. As such, it is designed for patients who may have difficulty swallowing or following a treatment regimen.

CDC Releases Draft Opioid Prescriber Guidelines

The Centers for Disease Control (CDC) on Friday released draft guidelines for opioid prescribing. The guidelines are designed to provide specific recommendations for the prescribing of opioid analgesics for adults in primary care settings. Among the recommendations include determining when to start initiate or continue opioids for chronic pain; opioid selection; dosage, duration, follow-up and discontinuation among other recommendations.

COMMITTEE REPORTS

Medical Examiner's Report

No report.

DEA Report

No report

Substance Abuse Report

No Report

Law Enforcement Report

Sgt. Thompson introduced himself as the new supervisor of the Drug Diversion Unit of the Delaware State Police. He looks forward to having a good working relation with the Committee and the Office of Controlled Substances.

Regulatory Committee Report

None

Legislative Committee Report

None

INSPECTION REPORT

None

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

PUBLIC COMMENTS
Ms. Patel spoke about the issue of patients often having a difficult time obtaining controlled substances from Medicaid sources once these medications have been prescribed legitimately from a practitioner.

EXECUTIVE SESSION
None

NEXT SCHEDULED MEETING
The next regular meeting will be held on December 2, 2015 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT
A motion was made by Dr. Kremer, seconded by Dr. Ruggles, to adjourn the meeting at 11:15 am. The motion carried.

Respectfully submitted,

Christine Mast
Administrative Specialist III
Office of Controlled Substances